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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,886	10/15/2003	Jesse H. Shaver	C73.12-0001	5948

27367 7590 05/11/2006

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EXAMINER	
WILLIAMS, DON J	
ART UNIT	PAPER NUMBER
2878	

DATE MAILED: 05/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/685,886	**Applicant(s)** SHAVER, JESSE H.
	Examiner Don Williams	**Art Unit** 2878

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1-37* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *15 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 14-30, 33, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya (6,585,723).

As to claim 1, Sumiya discloses a light source (11) to generate light; a first lens (15) to collimate the light from the light source (11); a second lens (18) receiving the collimated light transmitted through the first lens (15) and adapted to focus the light into a focal region in the substance (E). Sumiya fails to explicitly disclose an actuator. However, Sumiya discloses that the control unit (40) is connected to the driving circuit (46), the driving circuit (46) is directly coupled to the focusing lens (18), and a position sensor (photodetector, 23) operably coupled to the focusing lens (18) by receiving a reflected signal corresponding to the scanning of the substance (E). This arrangement causes a signal to be transmitted from the driving circuit to the focusing lens (18) allowing the focusing lens (18) to move back and forth along the optical axis, (see figure 2, column 3, lines 35-67, column 4, lines 1-17). It would have been obvious for one ordinary skill in the art to include such an arrangement as stated above to improve the oscillation or back and forth movement of the focusing lens and to monitor the position of the focusing lens (18) corresponding to the reflected light from the focal region of the substance (E).

As to claim 2, Sumiya discloses signal processing module (42) receiving a signal from the sensor (23) and providing an output indicative of properties of the substance (E) at the focal region, (see figure 2, column 4, lines 1-17, column 5, lines 47-60, column 7, lines 63-67, column 8, lines 1-8).

As to claim 3, Sumiya discloses a display (43) coupled to the signal processing module (42) to display the output, (see figure 2, column 5, lines 47-60).

As to claim 4, Sumiya discloses the signal processing module (42) is adapted to provide a feedback signal indicative of an acceptable working distance from the apparatus to the substance (E), (see column 9, lines 20-67).

As to claim 5, Sumiya discloses the output is indicative of thickness (525μm, 672μm, 540μm) of the substance (E), (see column 5, lines 47-67, column 7, lines 63-67, figure 7, column 8, lines 1-28).

As to claim 6, Sumiya discloses the output is indicative of opacity corresponding to the deteriorating thickness of the substance (E), (see column 1, lines 15-25, column 8, lines 1-8, column 9, lines 25-35).

As to claim 7, Sumiya discloses a filter (38) to form an image pattern of light from the light source (11), (figure 2, column 5, lines 4-12).

As to claim 8, Sumiya discloses image pattern with three focal spots spaced apart from one another, (see column 5, lines 15-24).

As to claim 9, Sumiya discloses the sensor (23) receives reflected light indicative of three focal spots and wherein a signal processing module (42) is coupled to the sensor (23) and calculates a relative phase difference of signals associated with each of the three spots and provides an output, (see figure 2, column 4, lines 1-17, column 5, lines 46-60).

As to claim 10, Sumiya discloses a beam splitter (14) to partially deflect light from the light source (11) and reflect light from the focal region of the substance (E) to the sensor (23), (see figure 2, column 3, lines 35-67, column 4, lines 1-17).

As to claim 14, Sumiya discloses the light source (11) is a laser, (see figure 2, column 3, lines (35-41).

As to claims 15, 36, Sumiya discloses (see fig. 2) pinhole apertures (13, 22) and second lens (18), (see column 4, lines 10-17). Sumiya fails to explicitly disclose a numerical aperture in a range from 0.47 to approximately 0.22. It would have been obvious for one ordinary skill in the art to use a numerical aperture capable of being set to the desired range in order to improve the focused beam of light incident on the substance or reflected from the substance.

As to claim 16, 17, 18, Sumiya fails to explicitly disclose calibration plate with known parameter as a thickness and opacity. Sumiya disclose a reticle plate with reference for alignment. It would have been obvious for one ordinary skill in the art to include a reticle plate with reference or known parameters to improve and acquire the precise location of the observation optical apparatus allowing precise alignment to the patient's eye to be achieved in order for the user of the observation optical apparatus to work effectively and efficiently without physical interference or contact between the optical observation apparatus and the patient's eye while removing the deteriorating opacity thickness corresponding to the cornea , (see figure 2, column 4, lines 45-52).

As to claim 19, Sumiya discloses a light source (11) to generate light; scanning mirrors (19, 20) for scanning the light across the substance (E), focusing lens (12, 18) for focusing light throughout a substance (E) at a focal region; Sumiya also discloses that the control unit (40) is connected to the driving circuit (46), the driving circuit (46) is directly coupled to the focusing lens (18), and a position sensor (photodetector, 23) operably coupled to the focusing lens (18) by receiving a reflected signal corresponding to the scanning of the substance (E). Sumiya fails to explicitly disclose an actuator. However, Sumiya discloses that the control unit (40) is connected to the driving circuit (46), the driving circuit (46) is directly coupled to the focusing lens (18), and a position sensor (photodetector, 23) operably coupled to the focusing lens (18) by receiving a reflected signal corresponding to the scanning of the substance (E). This arrangement causes a signal to be transmitted from the driving circuit to the focusing lens (18) allowing the focusing lens (18) to move back and forth along the optical axis, (see figure 2, column 3, lines 35-67, column 4, lines 1-17). It would have been obvious for one ordinary skill in the art to include such an arrangement as stated above to improve the oscillation or back and forth movement of the focusing lens and to monitor the position of the focusing lens (18) corresponding to the reflected light from the focal region of the substance (E).

As to claim 20, Sumiya discloses processing unit (42) for calculating a thickness of the substance (E), (see figure 8, column 8, lines 1-8).

As to claim 21, Sumiya further discloses control unit (40) and processing unit (42) for calculating or measuring opacity thickness corresponding to the substance (E), (see column 1, lines 15-25, column 8, lines 1-8).

As to claim 22, Sumiya discloses means for focusing includes a first lens (12) to collimate the light and a second lens (18) adapted to actuate in a direction parallel to the light and focus the light into a focal region of the substance (E), (see figure 2, column 3, lines 35-45, column 4, lines 1-17).

As to claim 23, Sumiya discloses filter (38) for filtering the light to form an image pattern, (see figure 2, column 5, lines 5-12).

As to claim 24, Sumiya discloses a method of quantitatively measuring characteristics of a cornea (E) by generating light with light source (11, 34); collimating the light with a first lens (15); focusing the light with a second lens (18) into a focal region of the cornea (E); actuating the second lens (18) along an axis of the direction of light to focus the light into the cornea (E) by receiving a signal from the driving circuit (46) that is directly coupled to the control unit (40), detector (23) sensing a portion of light reflected from the focal region of the cornea (E); and providing a signal indicative of the portion of light reflected, (see figure 2, column 4, lines 1-18). Sumiya fails to explicitly disclose a rate equal to or greater than 10 hertz. It would have been obvious for one ordinary skill in the art to set the actuating lens to a desired rate measured in hertz to improve the focus of the reflected image data corresponding to the cornea (E).

As to claim 25, Sumiya discloses displaying the signal indicative of the portion of light reflected on to the display unit (43), (see figure 2, column 5, lines 47-60).

As to claim 26, Sumiya discloses the output is indicative of thicknesses (525μm, 672μm, 540μm) of the substance (E), (see column 5, lines 47-67, column 7, lines 63-67, figure 7, column 8, lines 1-28).

As to claim 27, Sumiya discloses comparing the signal to a reference signal indicative of known thickness (525μm, 672μm, 540μm, (see column 5, lines 47-67, column 7, lines 63-67, figure 7, column 8, lines 1-28).)

As to claim 28, Sumiya discloses the signal is indicative of the opacity thickness of the cornea (E), (see column 1, lines 15-25, column 9, lines 5-35).

As to claim 29, Sumiya discloses comparing the signal to a reference signal indicative of a known opacity thickness corresponding to the cornea predetermined thickness standard, (see column 9, lines 5-35).

As to claim 30, Sumiya discloses a filter (38) for filtering the light to form an image pattern of light, (see figure 2, column 5, lines 5-12).

As to claim 33, Sumiya discloses partially deflecting light and reflecting light from the focal region (E) with a beam splitter (14), (see figure 2, column 3, lines 45-48).

As to claim 37, Sumiya discloses signal processing module (42) is adapted to provide a feedback signal indicative of an acceptable working distance between the second lens (18) and the cornea (E), (see column 9, lines 20-67).

Claims 11, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya in view of Yamakaji et al (6,637,880).

As to claims 11, 35, Sumiya fails to explicitly disclose a plastic aspheric lens. Yamakaji et al disclose a single vision aspheric plastic lens, (see column 12, lines 29-31). Sumiya and Yamakaji et al are related in that they both gather specific data corresponding to the cornea of the human's eye by scanning a focused laser beam across the cornea. It would have been obvious for one ordinary skill in the art to use an aspheric plastic lens as a focused scanning lens to improve the accuracy of image data being collected regarding the cornea of the human's eye.

As to claim 36, Sumiya discloses (see fig. 2) pinhole apertures (13, 22) and second lens (18), (see column 4, lines 10-17). Sumiya fails to explicitly disclose a numerical aperture in a range from 0.47 to approximately 0.22. It would have been obvious for one ordinary skill in the art to use a numerical aperture capable of being set to the desired range in order to improve the focused beam of light incident on the substance or reflected from the substance.

Claims 12 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya in view of Thorn et al (2003/0058404).

As to claims 12, 34, Sumiya discloses light sources (11, 34). Sumiya fails to disclose that the light source is a fiber optic coupler. Sumiya and Thorn et al are related in that they provide focused illumination of the substance or cornea. Thorn et al disclose that a light source is a fiber-optic illuminator (75), (see paragraph [0036]. It would have been obvious for one ordinary skill in the art to modify Sumiya to use a fiber-optic illuminator as the light source to improve the distribution of the deflected and reflected focused light from the focal region throughout the system.

Claims 13, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sumiya in view of Schmidt et al (4,407,008).

As to claims 13, Sumiya discloses a light source (11). Sumiya fails to explicitly disclose that a light source is a light emitting diode. Schmidt et al disclose light source (121) is a light emitting diode array. It would have been obvious for one ordinary skill in the art to modify Sumiya to include a light source emitting diode array (121) as disclosed by Schmidt to improve the illumination of the object, (see column 7, lines 64-66, figure 6, column 12, lines 35-42).

As to claim 31, Sumiya discloses irradiation spots. Sumiya fails to explicitly disclose three focal spots. Schmidt et al disclose illuminated focal points (P1, P2, P3, P4, P5) of specimen (44). It would have been obvious for one ordinary skill in the art to include illuminated focal points (P1, P2, P3, P4, P5) of specimen (44) as disclosed by Schmidt et al to improve the image pattern wherein each focal point being separated by the filter and displayed on each corresponding diode (D1, D2, D3, D4, D5) allowing each pattern to be laterally spaced from one another, (see figure 3, column 10, lines 38-49).

As to claim 32, Sumiya discloses receiving reflected light on irradiation spots. Sumiya fails to disclose three focal spots. Schmidt et al disclose a plurality of illuminated focal points. It would have been obvious for one ordinary skill in the art to include plurality of illuminated focal points (P1, P2, P3, P4, P5) corresponding to the signals of each diode (D1, D2, D3, D4, D5) which are laterally displaced a part from each other having a phase difference as disclosed by Schmidt et al to allow a wider viewing area of the cornea focus region to be analyzed in order to discover improvement methods for detecting opacity of cornea, (see figure 3, column 10, lines 30-49).

Response to Arguments

According to the applicant, Sumiya fails to teach or suggest an actuator and a position sensor for a second lens such that a signal is provided as a function of the position of the second lens. However, Sumiya does teach that the second lens (18) is arranged moveably back and forth along the optical axis and that (19, 20) are scanning mirrors which scan the infrared beam and the excimer laser beam over the cornea in two dimensional directions, (see column 3, lines 55-59). Sumiya also teach that the position to which the focusing lens (18) is moved is detected by the photodetector (23), (see Abstract). This arrangement causes a reflected signal to be transmitted from the control unit (40) to the driving circuit (46) and directly onto the focusing lens (18) allowing the focusing lens (18) to move back and forth or oscillate along the optical axis. Therefore, because of the reasoning set forth above, the rejection is proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Don Williams whose telephone number is 571-272-8538. The examiner can normally be reached on 8:30a.m. to 5:30a.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Georgia Epps can be reached on 571-272-2328. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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